UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,721	04/27/2005	Tomoya Takahashi	00005.001260	8744

5514 7590 08/07/2007

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,721	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Kyle A. Purdy	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) 1-14 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Claim for foreign priority is acknowledged. However, there is no certified translation filed. Therefore, the priority date is not granted. Instant application is only entitled the international filing date of 07/19/2001.

Claim Rejections - 35 USC § 112

112 First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of atopic dermatitis, does not reasonably provide enablement for prevention of atopic dermatitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

4. There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court *In re Wands* (8 USPQ2d 1400 (FACF 1986)). These factors are the quantity of experimentation; the amount of direction or guidance

presented in the specification; the presence or absence of working examples; the nature of the invention; the sate of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

5. The disclosure of the instant invention is directed to a method of preventing the onset of atopic dermatitis as set forth in claims 1-14. However, preventing atopic dermatitis using compounds of hydroxyproline and its derivatives is has not been found by the examiner in the prior art. Further, Applicant has not set forth in the specification how one is defining "preventing" the onset of atopic dermatitis. The definition of the word 'prevent' as set forth in Webster's Dictionary, when applied means 'to keep from happening, avert, or impede'. Hence, a skilled practitioner in the art could recognize that the prevention of atopic dermatitis indicates that the subject will **never experience** any characteristics associated with atopic dermatitis. The amount of guidance present in the specification and the absence of data indicating that atopic dermatitis is 'prevented' by administration of hydroxyproline, and the state of the prior art, Applicant is not enabled for the prevention of atopic dermatitis.
6. The efficacy of the claimed composition in preventing atopic dermatitis mentioned above cannot be predicted from a priori but must be determined on a case by case basis by painstaking experimental study and when the factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation in order to use this invention commensurate in scope with the claims.

112 Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 14 provides for the use of "hydroxyproline or N-acylated derivatives of hydroxyproline or a salt thereof for the manufacture or peroral preparation, food, feed, food additive or feed additive for prevention or treatment of atopic dermatitis", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

Instant Application over Published Patent

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examinewd application claim is not

patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 9-14 of U.S. Patent No. 7138386 (Nakagiri et al.; Date of Issue: Nov. 21, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6 and 9-14 are directed to a pharmaceutical composition which comprises an N-acylated hydroxyproline derivative or a salt thereof.

12. With respect to the functions recited herein any properties exhibited by or benefits provided by the composition are inherent and not given any patentable weight over the prior art. A chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims do not necessarily have to be present. Therefore, it would have been obvious to one of ordinary skill in the art to make a composition comprising hydroxyproline and its derivatives based on the claims present in '386 for treatment of atopic dermatitis.

13. Additionally, the recitation of 'comprising' in the claims of instant application allows for the inclusion of any other unspecific ingredients even in large amounts in disclosed composition.

Instant Application over Co-pending Application

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/529721 (Takeda et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 are drawn to a preventive or therapeutic agent for decubitus, which comprises an N-acylated derivative of hydroxyproline, or a salt thereof.

16. With respect to the functions recited above, any properties exhibited by or benefits provided by the composition are inherent and not given any patentable weight over the prior art. A chemical composition and its properties are inseparable. Thus, if the prior art teaches the identical chemical structure, the properties and/or claims Applicant discloses do not necessarily have to be present.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Makimoto et al. (US.6692754).

20. Makimoto et al. teaches hydroxyproline, a N-acyl derivative of hydroxyproline and the corresponding salts thereof, and a composition comprising hydroxyproline in amounts ranging from 0.01 to 5% by weight (see column 2, row 51-54). Further, the

N-acyl moiety linked to the nitrogen of hydroxyproline is stipulated to include an acyl group having preferably 1 to 24 carbons (see column 8, rows 1-9). Specifically disclosed is N-acetyl, N-propionyl, N-butyryl and N-isobutyryl derivatives of hydroxyproline. With respect to the functions recited, any properties exhibited by or benefits provided by the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties that Applicant discloses and/or claims are necessarily present. Further, the instant claims are directed to affecting a biochemical pathway with old and well-known compounds. It is well settled patent law that the elucidating a new mode of action does not impart patentable moment to otherwise old and obvious subject matter. In the instant invention, the claims are directed to an old and well known compound and composition comprising the same set forth in the prior art, albeit distanced by various biochemical functions. The disclosed functions within the instant application do not render the old and well-known compound and composition patentably distinct over the art.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coirre et al. (US.3932638) in view of Berger et al. (EP.0308278).

23. Coirre et al. teaches of using hydroxyproline and their derivatives for use in the treatment of inflammation and wound healing. Coirre discloses that hydroxyproline and its derivative are particularly useful in treating disease or wounds which affect the connective tissues (i.e. tendons, cartilage, skin, etc.). It is stated that hydroxyproline and its derivatives provide a means for replacement or regeneration of connective tissue (see column 1, rows 20-30). Further Coirre et al. discloses that the composition is non-toxic and is safe for oral administration (see column 1, row 50-54).

24. Coire et al. discloses only one species of acylated hydroxyproline (N-acetyl hydroxyproline) and fails to disclose the range the hydroxyproline or derivative comprises in the composition. Berger et al. teaches N-acetyl-, N-propionyl- and N-butyl hydroxyproline. Additionally, Berger et al. discloses that the cosmetic composition should include hydroxyproline and its derivatives between 0.1 to 20% by weight (see column 3, third paragraph).

25. Thus, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ a therapeutic composition comprising hydroxyproline and N-acylated derivatives thereof to skin suffering from atopic dermatitis.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached on Weekdays 8AM - 4PM E.S.T..

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or.571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kyle A. Purdy
TC 1600
July 25, 2007

***

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600